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TO: Richard Currie, Dave Haskell, Jim Sanborn, Michael Dong, Joshua Johnson, Tareq Formoli, Sally Powell

HSM-98014
[HSM assigned after issuance of memo]

FROM: Tom Thongsinthusak **[original signed by T. Thongsinthusak]**

DATE: April 24, 1998

SUBJECT: POSITION PAPER: STANDARD REFERENCE VALUES AND AVAILABILITY OF EXPOSURE FACTORS HANDBOOK (1997)

Standard reference values is one of the 11 harmonization issues considered by the NAFTA Technical Working Group on pesticides. Representatives from the U.S. EPA, Health Canada and DPR have adopted standard reference values as shown in the attached position paper. These standard values include body weights and inhalation rates for female and male children and adults, and life expectancy. Most of these values are listed in the final Exposure Factors Handbook (EFH) (1997).

John Worgan's colleagues at Health Canada are in the process of editing and formatting this position paper as well as the others for consistency. Please note that this position paper has not been signed off by authoritative bodies of the three agencies. I do not believe that there will be any significant changes in those listed values. I think that other reference values will be added to the paper in the next few years. Also, I will incorporate the adopted values in the revised HS-1612 document.

WH&S has received a copy of the final EFH (3 volumes). Presently, the Department library is processing this handbook. Charlene Evans will let us know once it is available in our library.

Attachment

cc: John Ross
John Sanders
(TCW/NAFTA/stdrf-pp)

POSITION PAPER
Issue: Standard Reference Values

Agency Approaches:

USEPA:

The USEPA's guidance for selecting standard reference values is dictated by the Exposure Factors Handbook (USEPA, 1997). In some cases, the Exposure Factors Handbook provides specific recommendations for selecting exposure factors. It is the Office of Pesticide Programs' policy to use these recommendations. Although the Exposure Factors Handbook recommends specific values, it also allows the assessor to select other values along the distribution. For example, the Exposure Factors Handbook recommends the arithmetic mean for adult surface area, but states that median values may be used *"when surface area distributions are preferred."* The Office of Pesticides harmonized the selection of the surface area for adults with Health Canada and California Department of Pesticide Regulation (DPR) and selected the median value. Therefore, to consistently use the median value, OPP has also selected the median body weight (i.e., 70 kg median body weight, not the Exposure Factors Handbook recommended mean value of 71.8 kg).

Health Canada:

a) Body weights: Health Canada's guidance for selecting standard body weights is dictated by CEPA's 1994 document entitled *Human Health Risk Assessment for Priority Substances* (CEPA, 1994). The overall standard body weight was set at 70 kg for adults 20 years and older. In cases where separate male and female body weights are required, the USEPA Exposure Factors Handbook (USEPA, 1995) was used. Male body weight was set at 78.1 kg (rounded to 78 kg), while female body weight was set at 65.4 kg (rounded to 65 kg).

b) Surface area: Health Canada's guidance for surface area was based upon the values presented in USEPA's Pesticide Assessment Guidelines - Subdivision U (USEPA, 1987).

c) Inhalation rate: For pesticide evaluations, Health Canada's guidance for inhalation rate was also based upon USEPA's Pesticide Assessment Guidelines - Subdivision U (USEPA, 1987). A value of 29 L/min was set for males performing light work (which was determined to be the equivalent of most pesticide activities). A value of 16 L/min was set for females performing light work.

Guidance for long-term exposure and/or other types of evaluations is dictated by CEPA's 1994 document entitled *Human Health Risk Assessment for Priority Substances*. The overall value for adults 20 years and older was set at 23 m^3/day.

d) Life expectancy: Life expectancy values were based on the USEPA Exposure Factors Handbook (USEPA, 1995). The overall figure is 70 years for males and females combined.

DPR:

The DPR's guidance document, HS-1612 (Thongsinthusak *et al*., 1993) shows standard reference values for adult body weights, surface areas, inhalation rates, and life expectancy. This document does not incorporate standard reference values for children; these values were adopted from USEPA (1985), USEPA (1990) or ICRP (1975) whenever they are applicable for exposure assessment.

a) Body weights and surface areas - DPR has adopted 50th percentile adult body weights and surface areas for adult males and females as reported in USEPA (1985). The adopted body weight (kg) and surface area (cm^2) for adult males are 75.9 and 19,400, and that for females are 61.5 and 16,900, respectively. Actual surface areas can also be estimated from an equation shown in USEPA (1985); parameters used in the equation are similar to those of Gehan and George (1970).

b) Inhalation rates - Inhalation rates for adult males and females were adapted from USEPA (1985). The rate (L/min) for resting, light, moderate, and heavy activities for males are 12, 14, 41, and 80, and that for females are 6, 8, 27, and 48, respectively.

c) Life expectancy - DPR adopted a life expectancy of 75 years (Bureau of the Census, 1991) for use in the estimation of lifetime average daily dosage.

Harmonization Status:

All Agencies are in agreement to use standard reference values shown in the attached Tables 1 (Adult Exposure Factors Recommended by NAFTA (USEPA, Health Canada, and California DPR)) and 2 (Child Exposure Factors Recommended by NAFTA (USEPA, Health Canada, and California DPR)).

Recommendations for Continued Progress:

The agencies will recommend changes whenever there are more appropriate standard reference values in the future.

(TCWP/NAFTA/Posit-c/stdrf-wp; 4/24/98)

Table 1. Adult Exposure Factors Recommended by NAFTA (USEPA, Health Canada, and California DPR).

Scenario	NAFTA Recommendations			
	Gender Specific			Comments
	Males	Females	Males & Females	
Body Weight (kg)	76.9 (round to 77)	62.4 (round to 62)	69.7 (round to 70)	Median values (USEPA, 1996). Value for Males & Females represents the average of the median body weights for males and females (USEPA, 1996). **NAFTA recommends using data for either sex or the average of both sexes, depending on whether sex was specified in the study. If both males and females were included in a study the male/female average should be used. Note: USEPA may use 71.8 kg (males and females) once the Exposure Factors Handbook is finalized. However, since the median value for surface area has been selected, the median body weight should also be used.**
Surface Area (cm^2)				Surface areas for individual body parts represent median values from USEPA (1996). Male upper arms represent the value for arms minus the value for forearms. Female upper arms and forearms are based on the data for arms, assuming the same ratio of upper arms to forearms as for males. Totals represent the sum of the median values for individual parts. Although it is not entirely correct to sum percentile values, it allows for consistency between the individual body parts data and the totals. Another appropriate method might be to use the median total surface areas, and the percentages of each body part to estimate surface areas for each part. This would also ensure consistency with total surface area. Values for males and females combined were calculated by averaging the data sets for the two groups. **NAFTA recommends using the median values for either sex or the average of both sexes, depending on whether sex was specified in the study. If both males and females were included in a study the male/female average should be used. The body surface areas in PHED V2.0 will be switched to the male surface area. Although USEPA (1996: 1997) recommends using the mean surface areas, it also states that the median values maybe used "when surface area distributions are preferred".**
Head	1,300	1,110	1,205	
Trunk (including neck)	7,390	5,790	6,590	
Arms	-	-	-	
Upper Arms	1,600	1,265	1,433	
Forearms	1,310	1,035	1,173	
Hands	990	817	904	
Thighs	3,820	3,260	3,540	
Lower Legs	2,560	2,180	2,370	
Total	20,280	16,597	18,440	

Scenario	NAFTA Recommendations			
	Gender Specific			Comments
	Males	Females	Males & Females	
Life Expectancy (years)	72.1	78.9	75	Average values, based on 1993 projections (USEPA, 1996; 1997). It should be noted, however, the expectation of life at birth has averaged above 70 years since before 1970, and has been approximately 75 years since 1982. These individuals are now almost 16 years old and could represent members of the agricultural work force. **NAFTA (and USEPA 1996: 1997) recommends using 75 years for adults, except in situations where gender is a factor.**
Working Lifetime (years)	-	-	40	Based on data in USEPA (1996; 1997) from Carey (1988) for the occupational group "farming, forestry, and fishing" that indicates a median tenure of 39.8 years for the 65+ age group. **NAFTA recommends using 40 years for agriculture, but not necessarily for antimicrobial uses. For the antimicrobial uses it is recommended that specific values from the Exposure Factors Handbook be used for various industries. USEPA (1997) allows occupational specific values such as the one selected by NAFTA.**
Chronic Inhalation Rates (m^3/day)	15.2	11.3	13.3	Based on the averages of Layton's (1993) three approaches for calculating inhalation rates (i.e., using average daily food energy equivalents, basal metabolic rates, and energy expenditure based on activity level), as presented in USEPA (1997). **A value for males and females combined is not provided in USEPA (1996; 1997), but is recommended by NAFTA by estimating the average of the male and females values (i.e., 13.3 m^3/day).**
Short- and intermediate-term Inhalation Rates (m^3/hr)				Based on the average of several studies (Adams, 1993; Layton, 1993; Linn et al., 1992) presented in USEPA (1997). NAFTA discussed reporting values for male and female, however, several methods were used to calculate the combined male and female values (e.g., age groups, time activity, and basal metabolic rates). Recalculating the male and female values separately is out of the scope of this project. If gender specific values are needed, NAFTA recommends using the values reported by Layton in USEPA (1997). The activities correspond to the following: **Rest** -lying down, **Sedentary** - sitting, pilot, driving a tractor, **Light** - flagger, mixer/loader (containers < 50 lb), pneumatic reel sprayer, lawn treatment, most harvesters, **Moderate** - mixer/loader (containers > 50 lb), backpack sprayer (greenhouse, hilly conditions, heavy brush), harvesters using ladders, **Heavy** - generally not applicable to occupational exposure to pesticides.
Rest	-	-	0.4	
Sedentary Activity	-	-	0.5	
Light Activity	-	-	1.0	
Moderate Activity	-	-	1.6	
Heavy Activity	-	-	3.2	

Table 2. Child Exposure Factors Recommended by NAFTA (USEPA, Health Canada, and California DPR).

Scenario	NAFTA Recommendations			
	Gender Specific			Comments
	Males	Females	Males & Females	
Body Weight (kg)				Mean values (USEPA, 1997), and median values in parentheses. The value for Males & Females represents the average of the median body weights for males and females. Mean values for males & females are not reported, but these values can be calculated by averaging the mean male and female values for each age group. **NAFTA recommends using the median values (reported in parentheses) to be consistent with the use of the median surface areas.**
6-11 months	9.4 (9.4)	8.8 (8.9)	(9.2)	
1 year	11.8 (11.7)	10.8 (10.7)	(11.2)	
2 years	13.6 (13.5)	13.0 (12.7)	(13.1)	
3 years	15.7 (15.4)	14.9 (14.7)	(15.1)	
4 years	17.8 (17.6)	17.0 (16.7)	(17.2)	
5 years	19.8 (19.4)	19.6 (19.0)	(19.2)	
6 years	23.0 (22.0)	22.1 (21.3)	(21.7)	
7 years	25.1 (24.8)	24.7 (23.8)	(24.3)	
8 years	28.2 (27.5)	27.9 (27.5)	(27.5)	
9 years	31.1 (30.2)	31.9 (29.7)	(30.0)	
10 years	36.4 (34.8)	36.1 (34.5)	(34.7)	
11 years	40.3 (37.3)	41.8 (40.3)	(38.8)	
12 years	44.2 (42.5)	46.4 (45.4)	(44.0)	
13 years	49.9 (48.4)	50.9 (49.0)	(48.7)	
14 years	57.1 (56.4)	54.8 (53.1)	(54.8)	
15 years	61.0 (60.1)	55.1 (53.3)	(56.7)	
16 years	67.0 (64.4)	58.1 (55.6)	(60.0)	
17 years	66.7 (65.8)	59.6 (58.4)	(62.1)	
18 years	71.1 (70.4)	59.0 (56.4)	(63.4)	

Scenario	NAFTA Recommendations			
	Gender Specific			Comments
	Males	Females	Males & Females	
Total Surface Area (cm^2)				Surface areas for individual age groups represent the recommended median values from USEPA (1996), except for the <1 and 1 < 2 year age groups which was taken from ICRP (1975). **NAFTA recommends using the <u>Male and female combined values</u> that are based on the average of the median male and female data, unless gender specific data are warranted.**
< 1 year	-	-	3925	
1 < 2 years	-	-	5275	
2 < 3 years	6030	5790	5910	
3 < 4 years	6640	6490	6565	
4 < 5 years	7310	7060	7185	
5 < 6 years	7930	7790	7860	
6 < 7 years	8660	8430	8545	
7 < 8 years	9360	9170	9265	
8 < 9 years	10000	10000	10000	
9 < 10 years	10700	10600	10650	
10 < 11 years	11800	11700	11750	
11 < 12 years	12300	13000	12650	
12 < 13 years	13400	14000	13700	
13 < 14 years	14700	14800	14750	
14 < 15 years	16100	15500	15800	
15 < 16 years	17000	15700	16350	
16 < 17 years	17600	16000	16800	
17 < 18 years	18000	16300	17150	

Scenario	NAFTA Recommendations						
	Gender Specific						Comments
	Males & Females						
Percentage of Surface Area of Body Parts (%)	head	trunk	arms	hands	legs	feet	Based on mean percentages for males and females combined from USEPA (1997). Values with *'s estimated using regression analyses.
< 1 year	18.2	35.7	13.7	5.3	20.6	6.54	
1 < 2 years	16.5	35.5	13	5.68	23.1	6.27	
2 < 3 years	14.2	38.5	11.8	5.3	23.2	7.07	
3 < 4 years	13.6	31.9	14.4	6.07	26.8	7.21	
4 < 5 years	13.8	31.5	14	5.7	27.8	7.29	
5 < 6 years	13.5*	34.7*	13.4*	5.46*	26.0*	7.04*	
6 < 7 years	13.1	35.1	13.1	4.71	27.1	6.9	
7 < 8 years	12.3*	34.4*	13.5*	5.44*	27.3*	7.13*	
8 < 9 years	11.7*	34.2*	13.6*	5.43*	27.9*	7.17*	
9 < 10 years	12	34.2	12.3	5.3	28.7	7.58	
10 < 11 years	10.7*	33.8*	13.7*	5.39*	29.2*	7.24*	
11 < 12 years	10.2*	33.6*	13.8*	5.38*	29.8*	7.27*	
12 < 13 years	8.74	34.7	13.7	5.39	30.5	7.03	
13 < 14 years	9.97	32.7	12.1	5.11	32	8.02	
14 < 15 years	8.81*	32.9*	13.9*	5.31*	31.7*	7.35*	
15 < 16 years	8.39*	32.7*	14.0*	5.27*	32.3*	7.37*	
16 < 17 years	7.96	32.7	13.1	5.68	33.6	6.93	
17 < 18 years	7.58	31.7	17.5	5.13	30.8	7.28	

Scenario	NAFTA Recommendations			
	Gender Specific			Comments
	Males	Females	Males & Females	
Chronic Inhalation Rates (m^3/day)				Specific Ages: Based on the data from Layton (1993) and presented in USEPA (1997) that uses energy intakes to estimate inhalation rates. The Male & Female combined values for the 9-11, 12-14, and 15-18 age groups were calculated from the values reported in USEPA (1997).
< 1 year	-	-	4.5	
1-2 years	-	-	6.8	
3-5 years	-	-	8.3	
6-8 years	-	-	10	
9-11 years	14	13	13.5	
12-14 years	15	12	13.5	
15-18 years	17	12	14.5	
Short- and intermediate-term Inhalation Rates (m^3/hr)	6 years old	-	-	Based on the mean from two reports (Astrand, 1952; Robinson, 1938) presented in USEPA (1985) and USEPA (1997). The ratios of ventilation rate and BW are highest for 6-year old male children. The ratios for 6-year old female children are not available.
Rest	0.4	-	-	
Light Active	0.8	-	-	
Moderate Active	2.0	-	-	
Heavy Active	2.4	-	-	

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